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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,695	11/14/2005	Margaret A. Pericak-Vance	5405.264	9656

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,695

Applicant(s)

PERICAK-VANCE ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,15-18,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-12,15-18,21 and 22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, 15, 16, 17, 18, 21 and 22, drawn to methods for screening a subject for asthma by detecting a polymorphic marker.

Group II, claims 10 and 11, drawn to oligonucleotide primers.

Group III, claim 12, drawn to a method for detecting a gene related to asthma.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the technical feature of invention I was known in the art at the time the invention was made. For example, Xu (American Journal of Human Genetics. 2001. 68: 1437-1446; cited in the IDS; see pages 1443-1444) and Dizier (American Journal Respiratory and Critical Care Medicine; cited in the IDS; pages 1815-1816) each teach polymorphic markers within the presently claimed regions and an association between these polymorphic markers

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and asthma susceptibility. Further, the primers of invention II were known in the art at the time the invention was made. For example, Bouffard (GenBank Accession NO. G20124; cited in the IDS) teaches primers "A" and "B" for amplifying polymorphic marker D7S1808, and thereby a segment of a chromosome bordered by D7S1808 and D7S2846. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention. Further, inventions I and III do not share a linking technical feature because each of the claimed methods involve the use of different reagents, have different outcomes and different effects.

3. Further restriction requirement applicable to invention I

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

D1S200, D1S1631, D5S2845, D5S2848, D5S589, D6S502, D6S503, D6S1043, D6S1007, D7S2195, D7S559, D7S1808, D7S2846, D8S113, D8S1132, D9S922, D9S253, D10S1221, D10S1432, D11S912, D11S4131, D13S1283, D13S779, D15S822, D15S643, D17S1298, D17S787, D19S1034, D19S165 and D21S1442; markers within three centimorgans of one of D1S200, D1S1631, D5S2845, D5S2848, D5S589, D6S502, D6S503, D6S1043, D6S1007, D7S2195, D7S559, D7S1808, D7S2846, D8S113, D8S1132, D9S922, D9S253, D10S1221, D10S1432, D11S912, D11S4131, D13S1283, D13S779, D15S822, D15S643, D17S1298, D17S787, D19S1034, D19S165 and D21S1442; and markers within a segment of chromosome 1 bordered by D1S200 and D1S1631; a segment of chromosome 5 bordered by D5S2848 and D5S589; a segment of chromosome 6 bordered by D6S502 and D6S503; a segment of chromosome 6 bordered by D6S 1043 and D6S 1007; a segment of chromosome 7 bordered by D7S2195 and D7S559; a segment of chromosome 7 bordered by D7S1808 and D7S2846; a segment of chromosome 8 bordered by D8S1113 and D8S1132; a segment of chromosome 9 bordered by D9S922 and D9S253; a segment of chromosome 10 bordered by D10S1221 and 10 1432; a segment of chromosome 11 bordered by D11S4131-qter; a segment of chromosome 11 bordered by D11S912-qter; a segment of chromosome 13 bordered by D13S 1283 and

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D13S779; a segment of chromosome 15 bordered by D15S822 and D5S643; a segment of chromosome 17 bordered by D17S1298 and D17S787; a segment of chromosome 17 bordered by D17S2196 and D17S1290; a segment of chromosome 19 bordered by D19S1034 and D19S1165; and a segment of chromosome 21 bordered by Pter-D21S1442.

Applicant is required, in reply to this action, to elect a single species or one particular combination of species to which the claims shall be restricted if no generic claim is finally held to be allowable. If Applicants elects one of the markers within 3 centimorgans of a marker recited in claim 1 and this marker is also within one the regions defined by claim 5, the response should indicate this fact. The response should further indicate which claims read on the elected polymorphic markers or combinations thereof, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 1-9, 15-18, 21 and 22 encompass the above listed species.
Currently, no claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited

markers consists of a different nucleotide sequence and occurs at a distinct location in the genome. Thereby, the distinct markers do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

4. Further restriction requirement applicable to inventions II and III

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a segment of chromosome 1 bordered by D1S200 and D1S1631; a segment of chromosome 5 bordered by D5S2848 and D5S589; a segment of chromosome 6 bordered by D6S502 and D6S503; a segment of chromosome 6 bordered by D6S 1043 and D6S1007; a segment of chromosome 7 bordered by D7S2195 and D7S559; a segment of chromosome 7 bordered by D7S1808 and D7S2846; a segment of chromosome 8 bordered by D8S1113 and D8S1132; a segment of chromosome 9 bordered by D9S922 and D9S253; a segment of chromosome 10 bordered by D 10S 1221 and D 10S 1432; a segment of chromosome 11 bordered by D 11S4131-qter; a segment of chromosome 11 bordered by D11S912-qter; a segment of chromosome 13 bordered by D13S 1283 and D13S779; a segment of chromosome 15 bordered by D 15S822 and D 5S643; a segment of chromosome 17 bordered by D17S1298 and D 17S787; a segment of chromosome 17 bordered by D17S2196 and D17S1290; a segment of chromosome 19 bordered by D19S1034 and D19S1165; and a segment of chromosome 21 bordered by Pter-D21S1442.

Applicant is required, in reply to this action, to elect a single species or one particular combination of species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response should further indicate which claims read on the elected segments, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

With respect to invention II, claims 10 and 11 encompass the above listed species. Currently, no claims are generic.

With respect to invention III, claim 12 encompasses the above listed species. Currently, no claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited nucleic acid segments consists of a different nucleotide sequence and occurs at a distinct location in the genome. Thus, polymorphisms and alleles within the segments are distinct from one another in terms of their nucleotide identity and location in the genome and their functional activity. Thereby, the distinct polymorphisms and alleles do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

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In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or **THIRTY DAYS**, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach

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the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634